



MONTANA STATE HOSPITAL POLICY AND PROCEDURE

INSTITUTIONAL REVIEW BOARD

Effective Date: July 28, 2004

Policy #: TX-24

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- I. PURPOSE:** To establish an Institutional Review Board (IRB) to review and approve research activities at Montana State Hospital involving or affecting hospital patients.
- II. POLICY:** All research activities involving or affecting hospital patients must be approved by the Montana State Hospital Institutional Review Board. The Board will convene on an “as needed” basis. The committee will be guided by ethical principals involving human subjects that include¹:
- A. *Respect for Persons.* That individuals should be treated as autonomous agents; and that persons with diminished autonomy are entitled to protection.
 - B. *Beneficence.* Persons are treated in an ethical manner not only by respecting their decision and protecting them from harm, but also by making efforts to secure their wellbeing. The two general rules formulated, as complementary expressions are (1) do not harm, and (2) maximize possible benefits and minimize possible harms.
 - C. *Justice.* The selection of subjects for research should be equitable and the fruits of the research should be distributed equitably.

Montana State Hospital acknowledges and accepts responsibilities for protecting the rights and welfare of patients involved in research activities and will ensure that all proposed projects comply with federal and state regulations.

Montana State Hospital recognizes that proper consideration must be given to:

- A. The potential risk to the subject(s);
- B. The anticipated benefits to the subject(s) and others;
- C. The importance of the knowledge that may be reasonably expected to result; and
- D. The informed consent process to be employed.

III. DEFINITIONS:

Institutional Review Board – An administrative committee designated to ensure protection of Montana State Hospital patients who are the subject of research studies.

¹ Adopted from the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, “*The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*”

Research – A structured scholarly or scientific inquiry to discover or check facts. Research differs from treatment in that the inquiry is carried out in accordance with experimental design principles and the outcome is uncertain.

IV. RESPONSIBILITIES:

Medical Director – To convene the committee and chair IRB meetings.

V. PROCEDURE:

- A. The Institutional Review Board will be comprised of the following members:
 - i. Medical Director (chair)
 - ii. Hospital Administrator
 - iii. Chief, Psychology Department
 - iv. Director, Quality Improvement
 - v. Attorney, Mental Disabilities Board of Visitors
 - vi. One Additional Physician or Licensed Psychologist appointed by the Medical Director
- B. Research proposals involving MSH patients will be reviewed by the Medical Director who will determine whether to convene an Institutional Review Board Meeting to review and approve the research proposal. The Medical Director will also determine whether the principle investigator or associate needs to appear before the committee to answer questions or explain the proposal. The Board may convene as often as necessary to approve proposals and oversee projects. The Board will meet at the conclusion of any project to review findings and adherence to all requirements.
- C. Approval will be granted by the committee reaching agreement (consensus) by all members that the proposal has merit and any concerns have been appropriately addressed. Any member of the committee may veto the proposal.
- D. The Committee must review procedures for research subjects or guardians to grant consent for participation in the project and must be satisfied that the process protects individual rights and allows for full and appropriate disclosure.
- E. Minutes of all meetings will be maintained and will include actions taken by the committee in response to proposals.
- F. This process does not replace or substitute for the responsibilities of the Mental Disabilities Board of Visitors to review all plans for experimental research involving persons admitted to a mental health facility (53-21-104, M.C.A.). The MDBOV is responsible for establishing their own review process and communicating approval or non-approval to the Hospital.
- G. Use of patient medical records in research activities will conform to requirements of the Montana Uniform Health Care Information Act (50-16-501 through 553, M.C.A.).

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In accordance with Montana statute, records may only be disclosed after the Institutional Review Board has determined the research project:

- i. Is of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure;
- ii. Is impracticable without the use or disclosure of the health care information in individually identifiable form;
- iii. Contains reasonable safeguards to protect information from improper disclosure;
- iv. Contains reasonable safeguards to protect against directly or indirectly identifying any patient in any report of the research project; and
- v. Contains procedures to remove or destroy at the opportunity, consistent with the purposes of the project, information that would enable the patient to be identified unless the institutional review board authorizes retention of identifying information for purposes of another research project.

VI. REFERENCES:

H. Montana Uniform Health Care Information Act (50-16-501 through 553 M.C.A.)

I. 53-21-104(2) M.C.A. – Powers and duties of mental disabilities board of visitors.

J. *The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research*

VII. COLLABORATED WITH:

Hospital Administrator
Medical Director
Chief, Psychology Department

VIII. RESCISSIONS: None

IX. DISTRIBUTION: All hospital policy manuals

X. REVIEW AND REISSUE DATE: July 2007

XI. FOLLOW-UP RESPONSIBILITY: Medical Director

XII. ATTACHMENTS: None

_____/____/____
Ed Amberg
Hospital Administrator

Date

_____/____/____
Thomas Gray, M.D.
Medical Director

Date